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July 19, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Response to FDA's Request for Comments on Improving Premarket Review and Approval of Food and Color Additives
Docket No. 00N-1262

The American Plastics Council hereby submits its comments in response to the Food and Drug Administration (FDA) request for comments on Improving Premarket Review and Approval of Food and Color Additives in the Center for Food Safety and Applied Nutrition published in the Federal Register of May 9, 2000 (65 Fed. Reg. 26215). The American Plastics Council (APC) is a major trade association for the U.S. plastics industry. APC is comprised of 26 of the leading plastics manufacturers in the United States, with many members having a strong, global market presence. APC's membership represents 80 percent of the U.S. resin production capacity.

To begin, APC commends FDA's efforts in implementing the Food Contact Substance Premarket Notification System (FCN) created by the Food and Drug Administration Modernization Act of 1997 as the major way to maximize efficiency in FDA's premarket approval processes. The FCN system provides an efficient and expedient means for approval of food contact substances, while continuing to ensure the safety of those substances. The FCN system is contemplated to take the place of the current food additive petition (FAP) and threshold of regulation (TOR) systems for the majority of food contact substances. The FCN system provides a benefit to both industry and the Agency, in that it allows FDA to devote the appropriate resources to clearing additional food contact substances, and it provides industry with a certain time frame for that approval. To continue the progress already made by the Agency, APC notes several areas where FDA could focus its efforts to ensure the success of the FCN system for both industry and the Agency.

FDA should utilize the additional funds received in fiscal year 2000 mentioned in the May 5, 2000 request for comments in several areas. One area where FDA should consider devoting additional resources is to expedite the process of disseminating information on cumulative estimated daily intakes (CEDI) and acceptable daily intakes (ADI) for food contact substances. The FCN process currently places the burden of establishing the CEDI of the notified substance on the notifier. While the notifier will likely have the information available to estimate exposure from the requested use, without information on the Agency's current CEDI for the material, it may not be

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possible for the notifier to determine an appropriate CEDI for the material including the notified use. Establishing an appropriate CEDI is critical, as this level determines the amount and nature of the data required to establish safety. In fact, it is possible the CEDI with the requested use would be high enough to necessitate the filing of a FAP. Knowing this in advance of submitting the FCN would save both industry and Agency resources.

Similarly, the ADI for a given material is of critical importance to the party submitting a notification. Again, while it is possible for the notifier to determine an ADI for the material based on the toxicological studies available to the notifier, the Agency may have additional studies or other information that would result in its establishing a different ADI. If the Agency is going to evaluate the notification using an ADI lower than that thought to be applicable by the notifier, it is possible that the notification will not show an adequate demonstration of safety. If this ADI information were available to the notifier prior to submitting the notification, for example on FDA's Internet site, this situation may be avoided as the notifier could choose not to submit the notification at all. This would result in a savings to both the notifier and the Agency, as neither would expend resources on attempting to establish the safety of the use where it is not appropriate to do so. FDA has indicated that both the CEDI and ADI information will be made public on the Agency's Internet site. APC supports this decision and encourages the agency to expedite the process as much as possible.

APC further requests the Agency devote some of the additional resources available to developing a guidance document on the preparation of Environmental Assessment (EA) documents for FCNs that do not qualify for a categorical exclusion under proposed 21 C.F.R. 25.32(i), (j), (k), (q), or (r). The Agency has prepared an interim guidance, included as Attachment 3 to the draft Guidance for Industry – Preparation of Premarket Notifications for Food Contact Substances: Administrative, for the preparation of an EA for an FCN for a material covered under those proposed regulations, for use until the proposed rule becomes final. In that document, FDA states that it is developing an environmental guidance document, to be made available through a notice published in the Federal Register, for those materials not covered by the exclusions. APC requests that the Agency devote the resources necessary to expedite this process, as the Agency has indicated that insufficient environmental information shall be grounds for not accepting an FCN. Food Additives: Food Contact Substance Notification System: Proposed Rule, 65 Fed. Reg. 43269, 43273 (July 13, 2000).

Also, as APC suggested in its initial comments in response to the Agency's proposed guidance documents on the FCN system, APC requests that FDA establish an electronic filing format for FCN submissions. APC commends the Agency for its decision to proceed with providing the FCN forms in a word processing format, such as Microsoft Word or WordPerfect, as well as PDF format. APC further suggests the Agency continue its efforts towards the establishment of an all-electronic submission for food contact notifications, and repeats its offer of participating in a pilot test of any proposed electronic filing system.

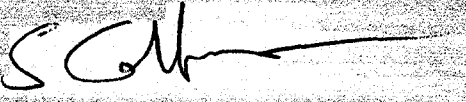
Another area where FDA could devote some of the additional resources available is to increase the pace and level of training for Agency staff working on the FCN program. APC notes that the initial round of training for Agency staff working on the FCN program was quite successful, with these personnel demonstrating an extensive knowledge of the process and procedures to be utilized for the FCN system. As the FCN system becomes more established, and more utilized, the pace of these submissions is likely to increase. To date, after six months of accepting FCNs and

almost 9 months of the system being effective, FDA has received less than 100 FCNs. While it may take some time for the pace of submission to reach the level the Agency predicts in its proposed rule on the FCN system, 65 Fed. Reg. 43276-77, the rate of submissions is sure to increase as industry becomes more familiar with the program. As FDA receives more submissions, this will require additional staffing to process the notifications within the 120 day statutory time limit. This may require Agency personnel who are able to "fill in" on FCN submissions during periods of peak activity, but are not devoted to the FCN program on a full-time basis. These Agency personnel must be adequately trained and familiar with the FCN system to accomplish this task in the limited time period, which does not allow room for a "learning curve." Also, as the number of notifications increases, there will be additional requests from industry for information and guidance on those submissions, including presubmission meetings with Agency staff. This also will require additional Agency personnel to timely and effectively respond to those requests. APC recommends that the Agency devote some of these additional resources received in fiscal year 2000 to meeting these requirements.

Finally, to help facilitate Agency understanding and processing of petitions and notifications for plastic food contact substances, APC makes the offer of participating in educational seminars to provide Agency personnel with additional information on plastics production and use. APC believes such a program would be of benefit to the public, the Agency, and industry, as it would allow for a more complete understanding of the issues involved in any food contact plastic application. APC would be interested in conducting these seminars as a continuing education program for all FDA personnel interested in such a program. Such education could help these personnel better understand the issues involved with a petition or FCN, which could lead to a more efficient review process. Also, such a seminar could assist industry in understanding the Agency's perspective on petitions and notifications, which would assist industry in preparing these submissions with all necessary information.

In conclusion, APC again commends the Agency for the progress it has already made in improving its review of food contact substances. The recently published proposed rule and draft administrative guidance document, 65 Fed. Reg. 43269 and 43377, are further evidence of FDA's commitment to establishing an efficient and productive system. APC offers these comments as further areas where the Agency could achieve even greater efficiencies for both industry and the Agency in its review of these premarket authorizations.

Sincerely,



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